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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/077,214	05/26/98	SCHMIDT W	0652.1710000

HM12/1016
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EXAMINER	
SCHWADRON,R	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/077,214	Schmidt et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Sep 21, 2001* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);

(b) ☐ they raise the issue of new matter. (See NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

4. ☒ Applicant's reply has overcome the following rejection(s): See enclosed NOTE

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See enclosed NOTE

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: None

Claim(s) objected to: N/A

Claim(s) rejected: 36, 38-40, 42-44, 48-50

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

11. ☒ Other: See enclosed NOTE

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

1. Regarding applicants comments about the finality of the previous Office Action, the amendment to claim 36 changed the scope of the ~~claim~~ claimed invention which necessitated a new art rejection. Applicants arguments fail to address the amending of said claim to recite "wherein said tumor cells have not been transfected with DNA". Said limitation in itself required a new search and necessitated a new rejection over the prior art. Said limitation was not previously recited in the claims under consideration. In addition, the amended claim 36 recited use of an "organic polycation" wherein said reagent was previously never recited in the claims. Said limitation itself required a new search and necessitated a new rejection over the prior art.

2. The rejection of claims 36,38-40,42-44,48-50 under 35 U.S.C. 102(a) as being anticipated by Schmidt et al. is withdrawn in view of the submitted certified copy of the English language translation of the foreign priority documents to which the instant application claims priority,

3. Claims 36,38-40,42-44,48-50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nair et al. in view of Fearon et al., Townsend et al., Van Der Bruggen et al. and prior art disclosed in the specification (see page 3) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Nair et al. disclose use of an organic polycation (eg. cationic liposomes) to deliver an MHC class I antigen to tumor cells (see abstract). Nair et al. teach that said method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I (see page 242, last sentence). Nair et al. do not disclose human tumor cells treated to express influenza virus peptide in the context of HLA class I. Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA (see entire paper). HA is a viral antigen. Townsend et al. teach that influenza HA or NP peptides are recognized by CTL in the context of MHC class I. Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo (see page 15, second paragraph). Van Der Bruggen et al. teach that said peptides can be delivered by vector (to infect APC) or by direct administration of the peptide to APC (see page 15, second paragraph). The art recognizes that tumors express numerous different tumor associated antigens (see prior art disclosed in specification, page 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Nair et al. disclose use of an organic

polycation (eg. cationic liposomes) to deliver an MHC class I antigen to tumor cells, Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA while Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo. In view of the fact that the cells disclosed by Nair et al. were treated with intact protein, said cells would have been expected to present multiple different peptides representing different epitopes derived from said molecule. It would also be expected that HA would encode a variety of different epitopes that would bind different HLA molecules found on MHC antigen heterozygous human tumor cells. One of ordinary skill in the art would have been motivated to do the aforementioned because of the demonstration by Fearon et al. of the use of HA transfected tumor cells as a tumor vaccine, while Nair et al. teach that their method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I. Regarding the "allogeneic" tumor vaccine limitation, the recitation of an intended use (eg. delivery to an allogenic host) carries no patentable weight in this product claim.

Regarding applicants comments about Nair et al., the recitation of an intended use carries no patentable weight in this product claim. The claimed human cells could be used in in vitro assays. Nair et al. disclose use of an organic polycation (eg. cationic liposomes) to deliver an MHC class I antigen to tumor cells (see abstract). Nair et al. teach that said method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I (see page 242, last sentence). In addition, Fearon et al. establish that the art recognized that antigen loaded tumor cells could be used in in vivo models (see abstract). Regarding applicants comments about the specification, both Nair et al. and Fearon et al. teach that the immunogenicity of tumor cells can be increased by adding additional exogenous antigens to said tumor cells. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success of producing the claimed invention because Fearon et al. teach use of HA transfected tumor cells as a tumor vaccine, while Nair et al. teach that their method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I.

4. No claim is allowed.

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-

4242.

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3974. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644